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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,242	08/24/1999	DAN E. ROBERTSON	DIVER1180-1	4972

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/382,242

Applicant(s)

ROBERTSON ET AL.

Examiner

Rebecca E. Prouty

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 February 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____


3. ☒ Applicant's reply has overcome the following rejection(s): see attached.
4. ☒ Newly proposed or amended claim(s) 21,31-33 and 44-47 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 21,31-33 and 44-47.Claim(s) objected to: 29.Claim(s) rejected: 26-28,34,35,38-42,48-50,52 and 53.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


Rebecca E. Prouty
Primary Examiner
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Applicant's amendments to the claims overcome all 112, 2nd paragraph rejections presented in the Final rejection. However, the amendments to Claim 48 (upon which Claims 49 and 50 depend) necessitate the reinstatement of the 112, 2nd paragraph rejection presented on page 3 of the non-final Office Action mailed 12/18/02 with regard to the phrase "stringent conditions".

Claims 26-28, 34, 35, 38-42, 48-50, 52 and 53 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the claims have been amended such that the claimed probes are described by both structural and functional features. However, this is not persuasive because the amendments to the claims do not include limitations on the function of **the claimed probes** but instead add functional limitations to the target nucleic acid to which the probe binds. As was previously explained the ability to bind to a particular sequence is not a function at all but merely defines the possible structure(s) of the compound and the presence of the ability to bind does not correlate to an ability to detect an

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esterase encoding sequence as the presence of structural similarity to a sequence **does not** provide an assurance of functional identity. The claimed oligonucleotides will bind to both esterase encoding sequences (such as SEQ ID NO:23) and non-esterase encoding sequences (such as variants of SEQ ID NO:23 with single substitutions which encode catalytically inactive proteins) under the recited hybridization conditions. As such the claimed genus of nucleic acids unlike that of example 14 of the guidelines is diverse in functional features.

Claims 26-28, 34, 35, 38-42, 48-50, 52 and 53 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a probe **consisting** of a fragment of SEQ ID NO:23 which will hybridize to SEQ ID NO:23 under stringent conditions and optionally a detectable label, does not reasonably provide enablement for any probe comprising a sequence which hybridizes to SEQ ID NO:23 or any nucleic acid having 90% or 95% identity to SEQ ID NO:23 and encoding an esterase under the recited conditions.

Applicants appear to believe that the amendments to the claims reciting that the target nucleic acid encodes an esterase addresses the concerns detailed in the previous Office Action. However, these limitations do not in fact overcome the previous

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rejection. Applicants asserted utility for these sequence is for the detection of esterase encoding sequences which is now expressly recited in the claims. Detection requires selective hybridization to the target. However, the recited hybridization conditions are very low stringency such that the scope of the claimed genus of probes is enormous. Most of the probes encompassed will hybridize under the recited conditions to an enormous number of possible sequences the vast majority of which will not encode an esterase protein. While the skilled artisan would understand that fragments of SEQ ID NO:23 itself would selectively hybridize to SEQ ID NO:23 under more stringent conditions, variant sequences (as also encompassed by the claims) would not and in fact would hybridize to some other sequence if selective conditions were utilized. As such the skilled artisan would require undue experimentation to use most of the probes claimed as asserted in the specification.

Claims 26-28, 48-49, and 52-53 remain rejected under 35 U.S.C. 102(a or b) as being anticipated by GenBank Accession No. X86487 or Kim et al.

Applicants argue that the amendment of the claims to recite "at least 30 nucleotides in length" will overcome the instant rejection. However, the nucleic acids of the cited references

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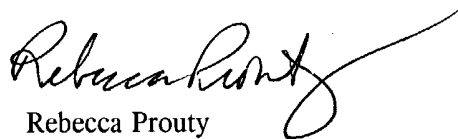
are each well more than 30 nucleotides in length and the limitation has no upper limit. As such it is not understood how this limitation will overcome the instant rejection.

Claims 21, 31-33, and 44-47 are allowable. Claim 29 would be allowable if amended to be in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Rebecca Prouty
Primary Examiner
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